ndc	ndc	descrip	form	misc1	vendor	DP number	cin	descrip	dev	type	code
00904-0321-60	904032160	SINUS RELIEF	TAB	30-325MG	MAJOR PHARMACEUTICALS	707724	2164424	SINUS RELIEF TB 100 MJR	80	PSE	S
00904-0668-15	904066815	DEXAPHEN SA	TAB	6-120	MAJOR PHARMACEUTICALS	698695	2163962	DEXAPHEN SA TB 120/6 10 MJR	80	PSE	S
00904-0668-95	904066895	DEXAPHEN SA	TAB	6-120	MAJOR PHARMACEUTICALS	698709	2163970	DEXAPHEN SA TB 120/6 20 MJR	80	PSE	S
00904-1324-20	904132420	CH ALL-NITE	LIQ	COLD/CG	MAJOR PHARMACEUTICALS	697630	2163731	ALL NITE COLD SR 120ML CHILD MJR	80	PSE	S
00904-3459-60	904345960	SIMPLET	TAB		MAJOR PHARMACEUTICALS	675024	2163665	SIMPLET TB 100 MJR	80	PSE	S
00904-3650-51	904365051	SYMPTOMATIC	TAB	COLD	MAJOR PHARMACEUTICALS	698652	2163947	COLD SYMPTOMS RELIEF TB 50 MJR	80	PSE	S
00904-5020-20	904502020	SUDOGEST CHD	SYP	30MG/5M	MAJOR PHARMACEUTICALS	707562	2164358	PS EUDO-GEST SR 4OZ MJR	80	PSE	S
00904-5053-24	904505324	SUDOGEST	TAB	30MG	MAJOR PHARMACEUTICALS	675598	2163681	PSEUDOGEST TB 30MG 24 MJR	80	PSE	S
00927-0187-07	927018707	KOLEPHRIN/DM	TAB		PFEIFFER	19257	1402882	KOLEPHRIN DM CL 30 PFR	80	PSE	S
00927-0224-63	927022463	KOLEPHRIN	TAB		PFEIFFER	19254	1402841	KOLEPHRIN CL 36 PFR	80	PSE	S
12463-0250-01	12463025001	NASABID	CAP	90-250CR	ABANA PHARMACEUTICALS	784800	1632488	NASABID 100S SEE#2514628	80	PSE	S
00045-0171-06	45017106	TYLENOL FLU	POW	NIGHTIM	MCNEIL CONSUMER	689602	2695161	Tylenol Flu Night PC6	999	PSE	S
00045-0174-10	45017410	TYLENOL FLU	CAP	NIGHTIM	MCNEIL CONSUMER	609820	2695021	Tylenol Flu Night 10	999	PSE	S
00045-0174-20	45017420	TYLENOL FLU	CAP	NIGHTIM	MCNEIL CONSUMER	609960	2695039	Tylenol Flu Night GC 20	999	PSE	S
00047-2900-23	47290023	TRIP/PSE/COD	SYP		WARNER CHILCOTT	581976	2070001	Tripol P-Ephed SR Fruit 16 oz.	999	PSE	S
00047-2932-23	47293223	MEDI-TUSS	SOL	#NAME?	WARNER CHILCOTT	582018	2070902	Medi-Tuss DAC SR STR Irs 16 oz	999	PSE	S
00084-0433-01	84043301	ANTIHIST NAS	TAB	DECONG	AMERICAN PHARMACEUTICAL CO.	466646	1841261	UN and Antinasl 100	999	PSE	S
00084-0433-24	84043324	ANTIHIST NAS	TAB	DECONG	AMERICAN PHARMACEUTICAL CO.	466638	1506021	UN and Antinasl TB 24	999	PSE	S
00084-0633-10	84063310	NIGHT TIME	SOL	CD FORM	AMERICAN PHARMACEUTICAL CO.	466859	1843036	UN night Colds Med El 10 oz	999	PSE	S
00217-0410-11	217041011	COPHENE-S	SOL		DUNHALL	310581	1854009	Cophene-S SR 480 ml	999	PSE	S
00276-1145-01	276114501	RESPINOL-G	TAB		MISEMER	480576	2017572	Respinol-G 400/60 100	999	PSE	S
00372-0038-01	372003801	HAYFEBROL	LIQ	SF	SCOT-TUSSIN	830607	2665800	HayFEBROL SF SL 30 ml	999	PSE	S
00372-0038-08	372003808	HAYFEBROL	LIQ	SF	SCOT-TUSSIN	830623	2665818	HayFEBROL SF SL 240 ml	999	PSE	S
00372-0038-16	372003816	HAYFEBROL	LIQ	SF	SCOT-TUSSIN	830631	2665826	Hayfebrol SF SL 480 ml	999	PSE	S
00426-8585-04	426858504	DECOHISTINE	SOL	EXPECT	MORTON GROVE PHARMACEUTICALS	736350	2695195	Decohistine10 mg 120 ml	999	PSE	S
00536-0432-90	536043290	CARBODEC DM	SYP		RUGBY	656283	2621316	Carbodec DM SR 3840 ML	999	PSE	S
00536-0432-97	536043297	CARBODEC DM	SYP		RUGBY	656291	2621324	Carbodec DM SR 120 ml	999	PSE	S
00536-0790-85	536079085	GUIATUSS DAC	SOL		RUGBY	610496	2256105	Guiatussin DAC SR 10 mg 480 ml	999	PSE	S
00563-2627-01	563262701	ZEPHREX LA	TAB	120-600	SANOFI PHARMACEUTICALS	362158	1981547	Zephrex LA TB 600 mg 100	999	PSE	S
00839-6404-63	839640463	CARDEC DM	SYP		H L MOORE	847038	2701878	Cardec DM TTT 15 ml	999	PSE	S
00839-6404-65	839640465	CARDEC DM	SYP		H L MOORE	847160	2701902	Cardec DM TTT 120 ml	999	PSE	S
00839-6471-06	839647106	DESIHIST SA	TAB	6-120	H L MOORE	871400	2704070	Desihist TB 120/6 100	999	PSE	S
00839-6471-16	839647116	DESIHIST SA	TAB	6-120	H L MOORE	871079	2704054	Desihist TB 120/6 1000	999	PSE	S
00839-6478-65	839647865	GUIATUSS DAC	SOL		H L MOORE	839850	2699940	Guiatuss DAC TTT 10 mg 120 ml	999	PSE	S
00839-6478-69	839647869	GUIATUSS DAC	SOL		H L MOORE	839647	2699908	Guiatuss DAC TTT SR 10 MG 480 ml	999	PSE	S
00839-6695-65	839669565	DIHISTINE	LIQ	EXPECT	H L MOORE	818658	2697431	Dihistine TTT EX 120 ML	999	PSE	S
00839-6695-69	839669569	DIHISTINE	LIQ	EXPECT	H L MOORE	818534	2697415	Dihistine TTT SR 10 mg 48- ml	999	PSE	S
00839-7079-69	839707969	TRIACIN-C	SYP		H L MOORE	856070	2702835	Triacin C TTT SR 480 ml	999	PSE	S
00839-7754-06	839775406	PSE/GG CR	TAB	120-600	H L MOORE	842605	2701167	Pseudophed/Guaf TTT 600 mg 100	999	PSE	S
00839-7785-65	839778565	HALOTUSSIN	SOL	DAC SF	H L MOORE	838144	2699716	Halotussin DAC 10 mg 120 ml	999	PSE	S
00839-7785-69	839778569	HALOTUSSIN	SOL	DAC SF	H L MOORE	837997	2699676	Halotussin DAC TTT SR 10 mg 480 ml	999	PSE	S
00839-7924-06	839792406	PSE/GG	CAP	60-300SR	H L MOORE	844233	2701597	Pseudoephed Guaf/TTT CD 300 mg 100	999	PSE	S
00839-7925-06	839792506	PSEUDO/GUAIF	CAP	120-250	H L MOORE	843474	2701209	Pseudoephed Guaf/TTT 250 mg 100	999	PSE	S
00839-7972-06	839797206	NASAL DECONG	CAP	12-120CR	H L MOORE	862045	2703320	Nasal Decong TTT 120-12 100	999	PSE	S
00839-7973-06	839797306	NASAL DCG PD	CAP	6-	H L MOORE	862177	2703361	Nasal Decong PED 60-6 mg 100	999	PSE	S
00904-0100-24	904010024	PSEUDO-GEST	TAB	30MG	MAJOR PHARMACEUTICALS	605085	2694776	U/L Pseudo Gest 30 mg 24	999	PSE	S
00904-0250-24	904025024	TRIPROL/PSE	TAB	2.5-60MG	MAJOR PHARMACEUTICALS	595560	2694206	U/L Aprodine 24	999	PSE	S
00904-0923-28	904092328	NOVAGEST/COD	SOL	EXPECT	MAJOR PHARMACEUTICALS	711128	2629160	Novagest EX 3840 ml	999	PSE	S
00904-1009-24	904100924	PSEUDOGEST	TAB	PLUS	MAJOR PHARMACEUTICALS	605000	2694768	U/L Pseudo Gest TB 24	999	PSE	S
00904-1322-21	904132221	ALL-NITE CLD	SOL	FORMUL	MAJOR PHARMACEUTICALS	595420	2694198	U/L All-nite Cold mint 180 ml	999	PSE	S
00904-1323-21	904132321	ALL-NITE CLD	SOL	FORMUL	MAJOR PHARMACEUTICALS	595390	2694180	U/L All-nite Cold Cherry 180 ml	999	PSE	S
00904-3650-51	904365051	SYMPTOMATIC	TAB	COLD	MAJOR PHARMACEUTICALS	599450	2694446	U/L Cold Symptom 50	999	PSE	S
11735-0032-11	11735003211	LANTAB	TAB		COLUMBIA DRUG	658081	2621811	Lan tabs 100	999	PSE	S
11735-0207-16	11735020716	LANTUSS-DM	SYP		COLUMBIA DRUG	405868	2009611	Lantuss DM SR 480 ml	999	PSE	S
11845-0861-01	11845086101	PSEUDO	TAB	30MG	MASON DISTRIBUTORS	763284	2696748	Pseudoephedrine tb 30 mg 100	999	PSE	S
11845-0936-01	11845093601	PSEUDO	TAB	60MG	MASON DISTRIBUTORS	763292	2696755	Pseudo Gtabs TB 60 mg 100	999	PSE	S
45985-0596-16	45985059616	CLORFED	SOL		STEWART JACKSON	360236	1981182	Clorfed 10 mg 480 ml	999	PSE	S
47028-0019-10	47028001910	LEMOHIST	CAP	PLUS	SENECA	654990	2621100	Lemohist Plus 1000	999	PSE	S

ndc	descrip	form	misc1	vendor	DP number	cin	descrip	dea	type	code
49483001610	PSEUDOEPHEDR	TAB	30MG	TIME-CAP LABS	693936	2627610	Pseudoephedrine TTT 30 mg 1000	999	PSE	S
50383008404	CO-HISTINE	SOL	DH	HI-TECH	898236	2677961	Co-histine DH 480 ml	999	PSE	S
50383008416	CO-HISTINE	SOL	DH	HI-TECH	898244	2677979	Co-histine DH 120 ml	999	PSE	S
50383008604	CO-HISTINE	SOL	EXPECT	HI-TECH	898210	2677946	Co-histine Exp	999	PSE	S
50383008616	CO-HISTINE	SOL	EXPECT	HI-TECH	898228	2677953	Co-histine Exp EX 480 ML	999	PSE	S
50383008804	GUAIATUSSIN	SOL	DAC	HI-TECH	898198	2677920	Guiatussin DAC SR 120 ml	999	PSE	S
50383008816	GUAIATUSSIN	SOL	DAC	HI-TECH	898201	2677938	Guiatussin DAC SR 480 ml	999	PSE	S
50383011404	GUIATUSS PE	SYP	30-100/5	HI-TECH	897353	2677482	Guiatussin - PE ST 120 ml	999	PSE	S
50383011504	ACTIVE	SYP	1.25-30	HI-TECH	896403	2677169	Active SR 120ml	999	PSE	S
50383011516	ACTIVE	SYP	1.25-30	HI-TECH	896411	2677177	Active SR 480 ml	999	PSE	S
50383011528	ACTIVE	SYP	1.25-30	HI-TECH	896420	2677185	Active SR 3840 ml	999	PSE	S
50383059328	BROMETANE DX	SYP		HI-TECH	896551	2677276	Brometane DX 3820 Ml	999	PSE	S
50383075128	CARBOFED DM	SYP		HI-TECH	896675	2677342	Carbofed DM SR 3840 ml	999	PSE	S
50732083816	NOVAHISTINE	SOL	#NAME?	ZENITH GOLDLINE SHREVEPORT INC	828971	2665347	NOVADYNE DMX SR 100/10 480 ml	999	PSE	S
50732083828	NOVAHISTINE	SOL	#NAME?	ZENITH GOLDLINE SHREVEPORT INC	828980	2665354	Novadyne DMX 100/10 3840 ml	999	PSE	S
50732087416	CH SUDACHEM	LIQ	30MG/5M	ZENITH GOLDLINE SHREVEPORT INC	829145	2665412	Sudachem Childs 6 mg/ml 480 ml	999	PSE	S
50732087428	CH SUDACHEM	LIQ	30MG/5M	ZENITH GOLDLINE SHREVEPORT INC	829153	2665420	Sudachem Childs SR 6 mg/ml 3840 ml	999	PSE	S
51301053004	ALLERPHED	SYP	1.25-30	GREAT SOUTHERN LABS	654078	2620680	Allerphed 120 ml	999	PSE	S
51301053204	DECOGEST	SYP	30MG/5M	GREAT SOUTHERN LABS	654302	2620912	Decogest 6 mg/ml120 ml	999	PSE	S
51301053304	DECOGEST	SYP	PLUS	GREAT SOUTHERN LABS	654310	2620920	Decogest plus SR 30/2 120 ml	999	PSE	S
53258017024	PSEUDOEPHEDR	TAB	30MG	VHA+PLUS	455377	1636382	V pseudoephedrine TB 30 mg 24	999	PSE	S
53746028801	TRIPROL/PSE	TAB	2.5-60MG	INTERPHARM	899038	2678332	Tripolidine/pseudo TB 100	999	PSE	S
53746028850	TRIPROL/PSE	TAB	2.5-60MG	INTERPHARM	899020	2678324	Tripolidine/pseudo TB 60	999	PSE	S
59741011504	BIOTUSSIN	SOL	DAC	BIO-PHARM	900117	2678811	Biotussin DAC EX 120 ml	999	PSE	S
59741011516	BIOTUSSIN	SOL	DAC	BIO-PHARM	900133	2678829	Biotussin DAC SR 480 ml	999	PSE	S
59741011704	BIOTUSS PE	SYP	30-100/5	BIO-PHARM	900184	2678878	Biotussin Pe EX 120 ml	999	PSE	S
59741011708	BIOTUSS PE	SYP	30-100/5	BIO-PHARM	900192	2678886	Biotuss Pe Ex 240 ml	999	PSE	S
59741011716	BIOTUSS PE	SYP	30-100/5	BIO-PHARM	900206	2678894	Biotuss Pe EX 480 ml	999	PSE	S
59741013430	BIODEC-DM	DRO		BIO-PHARM	900354	2679017	Biodec DM SF/AF DR 30 ml	999	PSE	S
59741013504	BIODEC-DM	SYP		BIO-PHARM	900362	2679025	Biodec DM SR 120 ml	999	PSE	S
59741013516	BIODEC-DM	SYP		BIO-PHARM	900370	2679033	Biodec DM SR 480 ml	999	PSE	S
59741013520	BIODEC-DM	SYP		BIO-PHARM	900388	2679041	Biodec DM SR 3840 ml	999	PSE	S
59741013704	BIOFED-PE	SYP	1.25-30	BIO-PHARM	900257	2678936	Biophed PE SR 120 ml	999	PSE	S
59741013708	BIOFED-PE	SYP	1.25-30	BIO-PHARM	900265	2678944	Biopehd PE SR 240 ml	999	PSE	S
59741013716	BIOFED-PE	SYP	1.25-30	BIO-PHARM	900273	2678951	Biophed PE SR 480 ml	999	PSE	S
59741013720	BIOFED-PE	SYP	1.25-30	BIO-PHARM	900303	2678969	Biophed PE SR 3840 ml	999	PSE	S
59741013804	BIOFED	LIQ	30MG/5M	BIO-PHARM	900311	2678977	Biophed SR 30 mg 120 ml	999	PSE	S
59741013808	BIOFED	LIQ	30MG/5M	BIO-PHARM	900320	2678985	Biophed SR 30 ml 240 ml	999	PSE	S
59741013816	BIOFED	LIQ	30MG/5M	BIO-PHARM	900338	2678993	Biophed SR 30 mg 480 ml	999	PSE	S
59741013820	BIOFED	LIQ	30MG/5M	BIO-PHARM	900346	2679009	Biophed SR 30 mg 3840 ml	999	PSE	S

DEA
COMPLIANCE MANUAL

APPENDIX F

DEA Correspondence

U.S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

JUN 25 1992

Ms. Sherry Haber
National Wholesale Druggist Association
105 Oronoco Street
Alexandria, Virginia 22314

Dear Ms. Haber:

It has been brought to the attention of the Drug Enforcement Administration (DEA) that some confusion exists regarding the proper completion of the DEA Form 222 with respect to the "number of lines completed." This letter is written to help alleviate some of the confusion.

Title 21 of the Code of Federal Regulations (CFR), section 1305.06(b) states that only one item shall be entered on each numbered line. It further states that the total number of items ordered shall be noted on the order form in the space provided. On the current version of the DEA Form 222, the aforementioned "space provided" is termed "number of lines completed." When the above requirements are followed to the letter, there is no discrepancy between the number of items ordered and the number of lines completed.

Problems in interpretation have been encountered when the purchaser either uses more than one line to describe an item or voids an item. In the first instance, the correct interpretation would be to list the number of items ordered on the form in the space labeled "number of lines completed." The DEA Form 222 will be revised in its next printing to rename the heading "number of items ordered."

The issue of voided lines on the order form is perhaps a bit less clear cut in its interpretation. In strictly interpreting the regulations, the only conclusion which can be reached which is not open for interpretation is that a supplier may not fill an order form which "shows any alteration, erasure, or change of any description" (21 CFR 1305.11(2)). In fact, instructions provided on the reverse side of the DEA Form 222 advise the purchaser

not to make erasures or alterations. They state that if an error should be made, all copies of the form should be voided and kept on file.

In addition, the regulations imply that only a supplier, not a purchaser, may void an item on a DEA Form 222. Section 1305.15(a) of the regulations states:

> A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier shall indicate the cancellation on Copies 1 and 2 of the order form by drawing a line through the canceled items and printing "canceled" in the space provided for number of items shipped.

Consequently, the supplier is the only individual that has the authority to indicate the cancellation on the order form.

A separate but related issue has also been raised regarding generic substitution of order forms. DEA policy does not preclude generic substitution of identical products provided that the name and National Drug Code number of the actual product shipped is reflected on the form. Therefore, it would be acceptable to make a substitution provided that the customer agrees to accept a generic rather than a brand name product, the generic product of a manufacturer other than the one specified or a brand name product rather than a generic one. Therefore, the purchaser will not be required to submit a new DEA Form 222 to accommodate such a change.

Please disseminate the enclosed information to the members of your organization in an effort to dispel any problems they are perhaps encountering with the form. Thank you for your attention to this matter.

Sincerely,

Gene R. Haislip
Deputy Assistant Administrator
Office of Diversion Control

Cardinal Health

TO: Clarence Crisp/Cdc
Paul Exley/Ovc
Ron Franks/Bos
Rick Gliot/Cdc
Ben Jones/Zan
Geoff Kirkham/Har
Carol Verrastro/Buf
Pete Westermann/Syr

CC: George Bennett

DATE: June 29, 1992

FROM: Steve Reardon/Bos Steve

SUBJ: Order Forms (DEA Form 222)

At a recent NWDA/DEA meeting that I attended, DEA issued the attached letter to further clarify their position on the proper completion of DEA Form 222 with respect to number of lines completed, voided or canceled lines, and generic substitutions. The regulatory interpretations are as follows:

- When two lines are used on an order form to describe one item, the number of lines completed at the bottom should be one. If two lines are used to order one item and "two" is entered in the number of lines completed, the order form must not be filled.

- A customer cannot void or cancel a line on the order form. If an order form is received from a customer with a voided or canceled line, the order form is considered defective and cannot be filled. Only a supplier may void an item on DEA Form 222. The customer may cancel a line by notifying the supplier in writing.

- It is acceptable to substitute generic product for generic product, generic product for brand name product, or brand name product for generic product provided that the products are equivalent, the name and the NDC number of the actual product shipped are reflected on the order form, and the purchaser agrees to the substitution.

Please read the letter for the specifics of these interpretations and pass the information on to the appropriate personnel in your division. Your customers should be notified regarding the consequences of their voiding or canceling a line.

DEA has informed their local offices of these interpretations, and you can expect regulatory enforcement to be consistent with the information contained in the letter.

If you have any questions, please call.

Attachment

Cardinal Health

TO: Clarence Crisp/Cdc
Paul Exley/Ovc
Ron Franks/Bos
Rick Gliot/Cdc
Ben Jones/Zan
Geoff Kirkham/Har
Carol Verrastro/Buf
Pete Westermann/Syr

CC: George Bennett

DATE: June 29, 1992

FROM: Steve Reardon/Bos Steve

SUBJ: Order Forms (DEA Form 222)

At a recent NWDA/DEA meeting that I attended, DEA issued the attached letter to further clarify their position on the proper completion of DEA Form 222 with respect to number of lines completed, voided or canceled lines, and generic substitutions. The regulatory interpretations are as follows:

- When two lines are used on an order form to describe one item, the number of lines completed at the bottom should be one. If two lines are used to order one item and "two" is entered in the number of lines completed, the order form must not be filled.

- A customer cannot void or cancel a line on the order form. If an order form is received from a customer with a voided or canceled line, the order form is considered defective and cannot be filled. Only a supplier may void an item on DEA Form 222. The customer may cancel a line by notifying the supplier in writing.

- It is acceptable to substitute generic product for generic product, generic product for brand name product, or brand name product for generic product provided that the products are equivalent, the name and the NDC number of the actual product shipped are reflected on the order form, and the purchaser agrees to the substitution.

Please read the letter for the specifics of these interpretations and pass the information on to the appropriate personnel in your division. Your customers should be notified regarding the consequences of their voiding or canceling a line.

DEA has informed their local offices of these interpretations, and you can expect regulatory enforcement to be consistent with the information contained in the letter.

If you have any questions, please call.

Attachment

Cardinal Health

TO: John Dewees
Paul Exley
Ron Franks
Rick Gliot
Ben Jones
Willard Lawrence
Doug Pace
Carol Verrastro
Pete Westermann

CC: George Bennett
Clarence Crisp

DATE: December 16, 1992

FROM: Steve Reardon

SUBJ: DEA Form 222

Please be advised that DEA has made changes on DEA Form 222 (sample attached). They are as follows:

- "No. of Lines Completed" has been changed to "No. of Items Ordered (Must Be Ten or Less)"
- Instruction #8 on the reverse side was changed *from:*

> 8. **Enter the number of items ordered – this should correspond to the number of lines used. If this number has not been entered, the form will be returned to you for completion before the supplier is allowed to fill it.**

to:

> 8. **Enter the number of *different* items ordered – this *generally* should correspond to the number of lines used. If a number has not been entered, the form will be returned to you for completion before the supplier is allowed to fill it.**

These changes were made in an attempt to facilitate compliance with 21 CFR 1305.06(b) which reads:

> (b) **Only one item shall be entered on each numbered line. There are ten lines on each order form. If one order form is not sufficient to include all items in an order, additional forms shall be used. Order forms for carfentanil etorphine dihydrochloride and diprenorphine shall contain only these substances. The total number of items ordered shall be noted on that form in the space provided.**

Please pass this information on to the appropriate personnel in your division. If you have any questions, please call.

Attachment

U.S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

APR 05 1993

Mr. Dan White
Director, Distribution Projects
and Regulatory Affairs
McKesson Drug Company
One Post Street
San Francisco, California 94104-5296

Dear Mr. White:

Reference is made to your recent letter in which you asked for clarification of the Drug Enforcement Administration's (DEA) policy regarding the "Number of Items Ordered" box on DEA Forms 222.

We had hoped to eliminate much of the confusion regarding the proper completion of order forms by changing the heading for this box from "Number of Lines Completed" to "Number of Items Ordered," but based upon your inquiry and others we have received, it is apparent that some confusion still exists.

In your letter, you cited as an example an instance where a purchaser has used five lines on a DEA Form 222 to order controlled substances. Line #1 and line #4 both contain entries for the same product and package size, i.e. "1 x 100 Ritalin Tab 5mg." You asked whether the "Number of Items Ordered" would be "five" or "four."

Section 1305.06 (c) of Title 21 of the Code of Federal Regulations (CFR) specifies that "An item shall consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item shall be made for each commercial or bulk container of different finished or bulk form, quantity or substance." It is our position, therefore, that in the example you cited, four items were ordered. If the purchaser in this case had erroneously indicated that five items had been ordered (most likely based on the fact that five lines had been completed), we would deem this to be a minor error which could be corrected.

It has always been our intent to keep all of our Diversion Investigators knowledgeable about interpretations of the Controlled Substances Act and implementing regulations as well as DEA policy. If you are aware of any inconsistencies in our field offices' interpretation of the CSA, the regulations or DEA policy, please bring it to Ms. Carter's or my attention so the situation can be rectified.

If I can be of further assistance, please let me know.

Sincerely,

G. Thomas Gitchel, Chief
Liaison and Policy Section
Office of Diversion Control

U.S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

MAY 18 1993

Ms. Diane P. Goyette
Director of Regulatory Affairs
National Wholesale Druggists' Association
P.O. Box 2219
Reston, Virginia 22090-0219

Dear Ms. Goyette:

This is in response to your letter of March 8, 1993, regarding the issues raised at the National Wholesale Druggists' Association's (NWDA) Regulatory Affairs Working Group meeting in San Antonio.

The issues raised at the meeting are important and we look forward to continuing to work with the NWDA on matters concerning compliance with Federal and state laws and regulations governing controlled substances. We have relayed the working group's concerns regarding consistency in the Drug Enforcement Administration's interpretation of policy to all of our field offices. We have also reminded them that responses to policy questions should be made in writing if requested by the registrant.

Thank you for allowing members of the Office of Diversion Control staff to meet with you. We believe that by sharing concerns and ideas to prevent the diversion of legitimate controlled substance, both DEA's mission and NWDA's needs will be met.

Sincerely,

G. Thomas Gitchel, Chief
Liaison and Policy Section
Office of Diversion Control

1973 1993

U.S. Department of Justice

Drug Enforcement Administration

JUN 23 1993

Mr. Larry L. Holland
Corporate Director
Security and Regulatory Compliance
Alco Health Services Corporation
P.O. Box 959
Valley Forge, Pennsylvania 19482

Dear Mr. Holland:

This is in response to your letter of April 22, 1993, in which you question the use of a former owner's Drug Enforcement Administration (DEA) registration by the new owner following the purchase of a pharmacy. There have been certain instances recently which have resulted in our reevaluating the circumstances under which these procedures may be used.

It is DEA's policy that upon purchasing a pharmacy the new owner must obtain a new DEA registration prior to dispensing controlled substances. However, we recognize that there may be occasions when, due to circumstances beyond the new owner's control, issuance of the appropriate state permits and, consequently, the new DEA registration may be delayed. In such situations, it may be permissible for the new owner to continue the business of the pharmacy under the previous owner's registration, provided certain conditions are met by both new and old owners.

The primary condition is that both the buyer and seller enter into a power of attorney that specifically sets forth the following:

1. The seller agrees to allow the controlled substance activities of the pharmacy to be carried out under the seller's DEA registration;

2. The seller agrees to allow the buyer to carry out the controlled substance activities of the pharmacy, including the ordering of controlled substances, as an agent of the seller;

3. The seller acknowledges that, as the registrant, they will be held accountable for any violations of controlled substance laws which may occur; and

4. The buyer agrees that the controlled substance activities of the pharmacy may be carried out under the seller's registration for no more than 45 days after the purchase date, which shall be recorded in the agreement.

In addition, the buyer must notify the appropriate local DEA office of the proposed use of the seller's DEA registration and, if requested, furnish a copy of the agreement. Should circumstances warrant, the local DEA office may withhold permission for the buyer to use the seller's registration number. The buyer cannot automatically assume that they will be authorized to utilize the seller's registration to conduct controlled substance activities.

With respect to your concerns regarding good faith verifications under such conditions, the best approach is to require that a copy of the power of attorney be provided with the copy of the registration certificate.

I trust the above adequately addresses your concerns. If you have any further questions or comments, please do not hesitate to contact this office at (202) 307-7297.

Sincerely,

G. Thomas Gitchel, Chief
Liaison and Policy Section
Office of Diversion Control

Cardinal Health

TO Tom Blaylock/*National Specialty Serv.*
John Dewees/*Marmac*
Paul Exley/*Ohio Valley*
Ron Franks/*Daly*
Rick Gliot/*Chapman*
Ben Jones/*Bailey*
Brian Landry/*Mississippi*
Doug Pace/*Florida*
John Roth/*Solomons*
Carol Verrastro/*Ellicott*
Pete Westermann/*Syracuse*

CC: George Bennett/*Dublin*

DATE: June 29, 1993

FROM: Steve Reardon/*Daly*

SUBJ: **DEA Policy**

Typically, local DEA offices are willing to provide registrants with regulatory policy interpretations but are hesitant to put these interpretations in writing. However, according to the attached letter, the field offices have recently been instructed to respond to policy questions in writing if requested by the registrant. In response to this new directive from Washington, our policy should be to ask for all interpretations of DEA regulations and policies or approvals of procedures for your operation to be put in writing. This practice will protect us against potential violations that could result when being inspected by DEA investigators who disagree with the interpretation or are new to the local office. If the local office is hesitant to put something in writing, please feel free to provide them with a copy of this letter or contact me, and I will handle it.

If you have any questions, please call.

Attachment

Cardinal Health

TO: Sales and Operations Personnel
Linda Zarlengo

CC: George Bennett
Pete Westermann

DATE: August 25, 1993

FROM: Steve Reardon

SUBJ: **Change of Pharmacy Ownership: DEA Policy**

Change of pharmacy ownership and continuing operation on a previous owner's DEA registration is an issue which has created ongoing confusion and inconvenience for us and our customers because of varying local DEA interpretations as to whether or not this is allowed.

DEA Headquarters recently documented DEA's official policy in the attached letter, which states that continued operation is permissible when certain conditions are met by both the current and previous owners.

The primary condition is that both the buyer and seller enter into a power of attorney that specifically sets forth the following:

1. The seller agrees to allow the controlled substance activities of the pharmacy to be carried out under the seller's DEA registration;

2. The seller agrees to allow the buyer to carry out the controlled substance activities of the pharmacy, including the ordering of controlled substances, as an agent of the seller;

3. The seller acknowledges that, as the registrant, they will be held accountable for any violations of controlled substance laws which may occur; and

4. The buyer agrees that the controlled substance activities of the pharmacy may be carried out under the seller's registration for no more than 45 days after the purchase date, which shall be recorded in the agreement.

Prior to selling to the new owner, you should obtain a copy of the power of attorney and file it with the copy of the previous owner's DEA registration certificate.

In addition, you must monitor the 45-day limit on controlled substance activity imposed as part of this policy.

If you have any questions, please call.

Attachment

Cardinal Health

TO Sales and Operations Personnel

CC: George Bennett

DATE August 25, 1993

FROM Steve Reardon

SUBJ Mid-Level Practitioners (MLPs)

The Drug Enforcement Administration (DEA) published a final rule in the June 4 Federal Register establishing a new category of DEA registrants, *mid-level practitioners (MLPs)*. The rule defines MLP as "an individual practitioner... other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice." Examples of MLPs include nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants.

MLPs will now be registered with DEA, but their authority to prescribe, dispense, and order controlled substances is granted by the state in which they practice and varies greatly among the states and types of MLPs (see attached). The final rule places responsibility for verifying this authority on the supplier, a complicated task at best.

I don't believe MLPs represent a significant new class of customers who would generate large volume sales and, because of the compliance difficulties posed by the authority verification responsibility, recommend that we do not sell directly to them. However, if this turns out not to be the case, we can reevaluate this position.

Please pass this information along to the appropriate staff in your division. If you have any questions, please call.

NOTE: The new MLP registration number will begin with the letter "M" rather than the letters "A" or "B" currently used for traditional practitioners.

Attachment

Distribution:

Denzel Bibey
Dave Blaylock
Tom Blaylock
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Carol Verrastro
Pete Westermann

NWDA

Dwight A. Steffensen, Chairman of the Board
Ronald J. Streck, President & CEO

National Wholesale Druggists' Association

P.O. Box 2219, Reston, VA 22090-0219 Fax # 703/787-6930
1821 Michael Faraday Drive, Suite 400, Reston, VA 22090-5348 • 703/787-0000

August 20, 1993

TO: Active Member CEO's
Government Affairs Committee
Regulatory Affairs Working Group

FROM: Diane Goyette
Director of Regulatory Affairs

Robin Pollini
Regulatory Analyst

SUBJECT: DEA Mid-level Practitioner Rule: Information on State Prescribing Authority

As previously reported to you, the Drug Enforcement Administration (DEA) published a final rule in the June 4 *Federal Register* establishing a new category of DEA registrants. Under this rule, mid-level practitioners (MLPs), such as physician assistants and nurse practitioners, will obtain and use their own DEA numbers to prescribe, dispense and order controlled substances, subject to state requirements. The rule went into effect on July 1, 1993. We have attached a copy of a June 1993, *Government Update* article outlining the new regulations (**Attachment A**).

MLPs will now be registered with DEA, but their authority to dispense controlled substances is granted by the state in which they practice. The final rule places the responsibility for verifying the degree of the MLP's authority to order and prescribe controlled substances on pharmacists, wholesalers and other parties in the distribution chain. Because prescribing authority varies so widely among states and types of MLPs, wholesalers need to be familiar with the restrictions imposed by each state that they service.

NWDA has developed the enclosed materials to familiarize you with the MLP prescribing authority in each state. We hope you will find them helpful in determining your obligations under the new DEA rule. The materials are based on information received from the National Association of Boards of Pharmacy, the American Academy of Physician Assistants, the American Nurses Association and various state authorities. In addition to the *Government Update* article, we have included the following:

Mid-Level Practitioner Prescribing Authority by State Chart (Attachment B) - This chart provides information on the prescribing authority, per state, for the following MLPs: doctors of homeopathy, physician assistants, advanced registered nurse practitioners, "other nurses" and optometrists. *This is only a partial list, containing information on the*

N·A

more commonly encountered MLPs. It should be noted that other practitioners may be covered under the MLP rule. For the purposes of this chart, the term "other nurses" includes clinical nurse specialists, nurse midwives, certified registered nurse anesthetists and various nurse practitioner specialists.

The chart takes each state and assigns the five MLP groups a number representing their prescribing authority under that state's regulations. MLPs with independent prescribing authority (category 1) or limited prescribing authority (category 3) are probably of the most concern to you as a wholesaler because these MLPs have the greatest degree of authority to prescribe. Dependent describing authority (category 2) in some states may also be of concern. A description of the categories appears at the beginning of the chart.

Notes on Dependent and Limited Mid-Level Practitioner Prescribing Authority, by State (Attachment C) - These notes accompany the chart to provide additional information on dependent and limited prescribing authority for physician assistants and nurses. Accordingly, each category 2 and 3 listing on the chart has a corresponding explanation in the notes. Many of the chart entries for other nurses "vary." Where this variation could not be covered in the notes, you will need to contact the state for more information.

State Contact Listings (Attachment D) - Because there are so many different types of MLPs and the prescribing authority for each of these MLPs varies widely by state, you may need to supplement the enclosed information by contacting the states for more information. The contacts at the state Boards of Pharmacy and state licensing agencies listed in this package should be able to answer any questions that you have regarding MLP prescribing authority.

We hope that the enclosed materials will assist you in responding to the requirements of the new DEA mid-level practitioner rule. As new information becomes available we will update these materials for your use. If you have questions regarding the enclosed materials or the mid-level practioner rule, please contact Robin Pollini, NWDA Regulatory Analyst, Ext. 242.

ATTACHMENT A

GOVERNMENT Update

National Wholesale Druggists' Association PO Box 2219, Reston, VA 22090 • 703/787-0000

Vol. 13 No. 6 June 1993

DEA Now Registers MLPs

Changes Could Pose New Burdens For Pharmacists, Wholesalers

The Drug Enforcement Administration (DEA) published a final rule in the June 4 *Federal Register* establishing a new category of DEA registrants. Under the new rule, which goes into effect on July 1, 1993, mid-level practitioners (MLPs) will obtain and use their own DEA numbers in dispensing controlled substances, subject to restrictions imposed by their state of practice.

The final rule defines an MLP as "an individual practitioner...other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice." DEA considers "dispensing" to include administering, prescribing and directly dispensing — delivering to the ultimate user — controlled substances. Examples of MLPs include nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants.

Until now, MLPs have used the DEA number of their supervising practitioner or institution, again subject to state requirements. The new MLP registration numbers will begin with the letter "M" rather than the letters "A" or "B," currently used for traditional practitioners, so they can be identified as a separate registration category.

Although MLPs now will be registered with DEA, their authority to dispense controlled substances is granted by the state in which they practice and varies widely. In the final rule, DEA acknowledges that verifying MLP dispensing authority will pose difficulties, but notes that it will be the responsibility of pharmacists, wholesalers and other parties in the distribution chain to contact the appropriate state officials to verify the degree of dispensing authority an MLP has been granted.

The burden of this verification is expected to fall primarily on pharmacists, who most commonly will receive orders for controlled substances in the form of individual prescriptions from MLP prescribers. However, drug wholesalers also can expect to handle orders for controlled substances bearing the M-designated DEA number. The unique number format should alert wholesalers to the fact that an MLP customer may or may not be authorized to order controlled substances in a given state. Since this authority varies so widely, wholesalers need to be familiar with the restrictions imposed by each state it services.

NWDA currently is compiling information on the states' laws governing MLPs, and will distribute this information to members as soon as it is complete.

ATTACHMENT B

MID-LEVEL PRACTITIONER (MLP) PRESCRIBING AUTHORITY BY STATE

This table provides information on state prescribing authority for a limited number of mid-level practitioners (MLPs). Please note that for the purposes of this chart, the term "other nurses" includes clinical nurse specialists, nurse practitioners and various nurse practitioner specialists. The codes used to describe the authority granted in each state are as follows:

1 - Independent prescribing authority: The MLP has independent authority to order or prescribe controlled and non-controlled substances.
2 - Dependent prescribing authority: The MLP may order or prescribe certain controlled substances under the supervision of a physician. See the notes that accompany this table for specific requirements by state.
3 - Limited prescribing authority: The MLP's prescribing authority is limited to certain types of drugs. See the notes that accompany this table for specific restrictions by state.
4 - The MLP may not order or prescribe controlled and non-controlled substances.
"vary" - Prescribing authority varies among different types of nurses. Contact the state for more information.

STATE	DOCTOR OF HOMEOPATHY	PHYSICIAN ASST	ADVANCED REGISTERED NURSE PRACTITIONERS	OTHER NURSES	OPTOMETRISTS
Alabama	4	4	4	4	4
Alaska	4	2	1	2	4
Arizona	1	2	1,2	4	1
Arkansas	1	4	4	4	1
California	4	4	3	vary	4
Colorado	4	2	2	vary	4
Connecticut	4	4	2	vary	4

STATE	DOCTOR OF HOMEOPATHY	PHYSICIAN ASST	ADVANCED REGISTERED NURSE PRACTITIONERS	OTHER NURSES	OPTOMETRISTS
Delaware	4	4	4	4	4
District of Columbia	4	2	2	2	1
Florida	4	4 (see notes)	2	4	1
Georgia	4	4	4 (see notes)	4	1
Hawaii	4	4	4	4	4
Idaho	4	2	1	vary	1
Illinois	4	4	4	4	4
Indiana	4	4	4	4	1
Iowa	4	2	3	4	1
Kansas	4	2	2	4	1
Kentucky	4	4	4	4	3,4
Louisiana	4	4	4	4	4
Maine	4	2	2	vary	4
Maryland	4	4	2	vary	4
Massachusetts	4	2	4	vary	4
Michigan	4	2	2	2	4
Minnesota	4	2	2	vary	4
Mississippi	4	4	2	vary	4
Missouri	4	2	4	4	1

STATE	DOCTOR OF HOMEOPATHY	PHYSICIAN ASST	ADVANCED REGISTERED NURSE PRACTITIONERS	OTHER NURSES	OPTOMETRISTS
Montana	4	3	1	vary	1
Nebraska	4	2	2	2	1
Nevada	1	2	2	4	4
New Hampshire	4	2	1	vary	4
New Jersey	4	4	4	vary	3
New Mexico	4	2	2	vary	1
New York	4	2	1	vary	4
North Carolina	4	2	2	vary	1
North Dakota	4	2	2	2	1
Ohio	4	4	4	vary	1
Oklahoma	4	4	4	4	3
Oregon	4	2	1	vary	1
Pennsylvania	4	4	4	4	4
Puerto Rico	4	4	4	4	4
Rhode Island	4	2	3	vary	1,4
South Carolina	4	2 (see notes)	2	vary	4
South Dakota	4	2	2	4	1
Tennessee	4	4	2	vary	1
Texas	4	2	2	vary	1

STATE	DOCTOR OF HOMEOPATHY	PHYSICIAN ASST	ADVANCED REGISTERED NURSE PRACTITIONERS	OTHER NURSES	OPTOMETRISTS
Utah	4	2	2	vary	2
Vermont	4	2	1	vary	4
Virginia	4	4 (see notes)	2	vary	1,4
Washington	4	2	1	1	4
West Virginia	4	2	3	4	4
Wisconsin	4	2	4	4	4
Wyoming	4	2	1,2 (see notes)	4	4